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RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DIDIER TRONO and MACIEJ WIZNEROWICZ

Appeal 2007-4320
Application 10/720,987
Technology Center 1600

Oral Hearing Held: April 8, 2008

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

ON BEHALF OF THE APPELLANTS:

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The above-entitled matter came on for hearing on Tuesday, April 8, 2008, commencing at 9:25 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, 9th Floor, Hearing Room A, Alexandria, Virginia, before Kevin E. Carr.

THE USHER: Calendar number 7, appeal number 2007-4320, Mr. Parker.

JUDGE ADAMS: Thank you.

Good morning, Mr. Parker.

MR. PARKER: Good morning, Your Honors.

JUDGE ADAMS: We are familiar with your record. You have 20 minutes, and you can start with spelling your name into the record. We'd appreciate it.

MR. PARKER: Yes, my name is David Parker, D-a-v-i-d, P-a-r-k-e-r.

First, Your Honor, I know that I did not make a specific request for pens on board.

JUDGE ADAMS: Are there any markers over there?

MR. PARKER: But, there aren't any markers.

JUDGE ADAMS: Are they underneath the podium?

MR. PARKER: If I may approach it here.

JUDGE ADAMS: There's none under the podium?

MR. PARKER: No. There's a couple, if he's not picky about colors.

JUDGE ADAMS: We don't mind the colors.

MR. PARKER: If acceptable to Your Honors, I would like to proceed and go directly to the obviousness rejection.

JUDGE ADAMS: Well, we have a few questions about the utility rejection, the 101.

MR. PARKER: The 101? Okay.

JUDGE ADAMS: I guess what it comes down to is, if you take a look at claim 47.

MR. PARKER: Right.

JUDGE ADAMS: And the issue here, as we understand it, is the claim reads on human, and your position is, well, no. It doesn't. Just as a windshield wiper doesn't read on a whole car.

MR. PARKER: I think the examiner would be obligated to point to some human that they claim does cover.

JUDGE ADAMS: Okay, so I guess the concern we have here is what is a fertilized oocyte?

MR. PARKER: A fertilized oocyte is a single cell that has been fertilized, a gamete that has been fertilized, so that then has a full complement of chromosomes, but it is still a single cell.

JUDGE LEBOVITZ: Is it an embryo?

MR. PARKER: At that point in time, I'm not sure precisely of the definition of "embryo," Your Honor. I don't know whether it has to divide at least once.

JUDGE LEBOVITZ: Well, this just says "fertilized", right? So, fertilized, as you said, means it has the full complement, so that doesn't preclude it from starting to divide, let's say.

MR. PARKER: Well, I would argue that it's still an oocyte. All right? So that means a cell that has been fertilized. Now, once it is divided once, I don't think it's any longer a cell. That's my definition. Frankly, I mean, the rejection goes away by putting in isolated.

JUDGE LEBOVITZ: Okay.

MR. PARKER: But, it's a very interesting issue.

JUDGE LEBOVITZ: It certainly is.

MR. PARKER: And it's one that I think raises a lot of interesting discussion. It's not of critical importance to us. I'm not trying to belittle it. It's an important issue because the consequences are very big. And that is if you have a claim to a recombinant DNA molecule, does that cover a human, potentially cover a human?

Well, one could argue we don't know the human right now that has a recombinant DNA molecule in it, but I do a lot of work for biotech companies that are involved in gene therapy. If that person has a tumor that it's received a nucleic acid; and, now you have a patent on a nucleic acid module and a vector. It doesn't have to stay isolated if it's a vector, but that vector could well be inside a human. Now, is that claim precluded because it reads on a human? That's an interesting issue.

JUDGE LEBOVITZ: Can I ask another question?

MR. PARKER: Yes, Your Honor.

JUDGE LEBOVITZ: This is kind of an unfair question, but is the Patent Office giving out claims to, just say, a human embryo, to your knowledge?

MR. PARKER: You know, I think the closest that comes to that is the recent stem cell case?

JUDGE LEBOVITZ: Yes.

MR. PARKER: And that was recently just allowed out of reexamination. And that claim there certainly rates on human stem cells. But what I don't recall there, Your Honor, is whether that claim says "isolated" or "purified," or anything like that. Because I think we would all agree that if those words were there, the issue goes away. I would like to go to the other rejection.

(Laughter.)

MR. PARKER: This is a kind of a complicated case, a little bit, and if I may approach the board, I am likely to draw a little bit about what the claims have been, and it takes me a while to get it in my head straight. Right. But the claim 1 is dawn to, and this is just my way of drawing DNA, so we have a Si RNA coating region. It's also called cell-stranded RNA. And these are small RNA molecules that have been discovered to reduce the transcription of particular genes. These are genetic inhibitory molecules.

My claim requires that this structure be under the control of a pol 3 promoter. Now, pol 3 promoter specifies that a polymerase 3 will attach and transcribe the Si RNA. There are three different RNA polymerase. There's RNA pol 1, pol 2, pol 3. Pol 1 specifies ribosomal RNA transcription, rRNA. Pol 2 is really all cellular genes, cellular or structural genes; and pol 3 are primarily tRNA. And the claim also specifies, and I'm going to go in terms since the written description takes directions within this drawing, I'm going to talk our preferred embodiment just for purposes of illustration.

In our preferred embodiment, we have here what is called a Tet operator, and the Tet operator is controlled. Now, here is the key part of the invention. By a Tet repressor, TetR, used to what is called a KRAB sequence. Now, the key thing is here it has a double whammy in its repression. So in the absence of Tetracycline, does that repression bind to the Tet operator region and it prevents Pol 3, rRNA polymers 3, from binding to the Pol 3 recognition site in transcribing. So without anything added to this system, expression of the Si RNA is shut off.

JUDGE LEBOVITZ: Is that the same promoter in the Deuschle reference?

MR. PARKER: No; it's not. The Deuschle reference is. That's the Tet operator, but the promoter in Deuschle.

JUDGE LEBOVITZ: Oh, excuse me. I meant operator.

MR. PARKER: Right. It's the same operator as used by Deuschle. But we have a separate whammy here. This is the DNA binding domain. Now, this is the repressor domain, which apparently exerts a specific effect on Pol 3, so it gives it a double whammy; not only prevents it from binding, but it prevents any little bit from perhaps binding here and going off.

JUDGE ADAMS: So the KRAB site specifically interacts with Pol 3?

MR. PARKER: Pardon?

JUDGE ADAMS: The KRAB site specifically interacts with Pol 3?

MR. PARKER: That's our belief.

JUDGE ADAMS: It interacts with Pol 3?

MR. PARKER: Yes, we know that from the prior art.

JUDGE ADAMS: So it's not specific?

MR. PARKER: Well, that's the issue before us in my opinion.

JUDGE ADAMS: And specific or not?

MR. PARKER: And whether the prior art teaches that it interacts and has the potential for interacting with Pol 3, I submit that if you read the prior art, which I am going to do in just a second, that it will show that the prior art tells you you need to use a Pol 3, to use the test system or the Tet KRAB system.

JUDGE ADAMS: And you view the Pol 2, I believe.

MR. PARKER: Pol 2, right.

JUDGE ADAMS: I think you said Pol 3.

MR. PARKER: I'm sorry, Pol 2. Right.

JUDGE ADAMS: I'd hate to get you down a track you didn't want to get on.

MR. PARKER: That's right. No, Your Honor.

So I'd like to focus on two references, which I think are the primary references here for consideration. The first is the Giordano reference which we've attached as our exhibit 6. And Giordano is European 1,229,134. Now, Giordano, I'd like to just read the title. Giordano talks about "Use of post-transcriptional gene silencing for identifying nucleic acid sequence that modulate the function of a cell."

And, if you read the abstract, it says, "Described herein are methods for identifying nucleic acid sequences that modulate the function of a cell's expression of a gene and biological activity of a target polypeptide. The methods involve the use of double-stranded RNA-expression libraries, etcetera. So, it's talking about these kinds of sequences, identifying these kinds of sequences.

JUDGE ADAMS: For the record, these kinds of sequences, the Si RNA or double-stranded RNA?

MR. PARKER: R double-stranded. Right.

JUDGE ADAMS: It teaches a construct that has Pol 1, Pol 2, Pol 3 or a variety of different promoter elements linked to Si RNA and double-stranded RNA.

MR. PARKER: Yes. I agree with that totally.

JUDGE ADAMS: In a cell?

MR. PARKER: And, it teaches it in a cell.

JUDGE ADAMS: In an oocyte, or gamete?

MR. PARKER: I don't know about that, Your Honor.

JUDGE ADAMS: Can I show you that?

MR. PARKER: But I think it does. I think the examiner found something presenting that.

JUDGE ADAMS: Okay. Thank you.

MR. PARKER: So then I would like to turn specifically to the section the examiner is relying on, paragraph 11. Now, paragraph 11 talks about these constructs for finding the Si RNAs are characterizing them can be in the form of an expressing vector. And that's the second paragraph of paragraph 11. It looks like paragraph 11 has two paragraphs. It says:

"The nucleic acid is contained in a vector, for example, a double-stranded RNA expression vector." That's at line 25, of column 3. And, indeed, down at line 45 to the bottom of column 3, it starts talking

about the different types of promoters that one can use. And it says -- I'm reading at line 45 -- it mentions at least one RNA polymerase 3 promoter. So I would agree. It says that that's one potential embodiment. It goes on to say the promoter may also be a T7 promoter. Alternatively, the promoter may be an SP6 promoter, and so on and so forth.

Now, in the sentence bridging columns 3 and 4, it says in other embodiments "the promoter is a mitochondrial promoter." Line 5 of column 4 is alternatively, "the promoter is an inducement promoter." So it's saying alternative to the foregoing, it could be an inducible promoter. Go down to line 12, it mentions specifically a Tet promoter. Now, so I agree it mentions every type of promoter, but to understand what it means by this Tet promoter, I submit this inducible promoter.

I submit you have to then go to paragraph 110 at column 33, and this is the section here that's entitled, "Inducible or repressible transcription vectors for the generation of dsRNA expression library." And there at lines 19 to 21 it says: "Talking about these inducible and repressible regulator systems." At line 19 to 21 it says: "In addition, these factors also carry protein domains that transactivate or transrepress the RNA polymerase 2." It doesn't say polymerase 3. It doesn't say polymerase 1. It doesn't say SP6. Harkening back to paragraph 11, it talked about many different alternatives, and those were mentioned not as alternative embodiments.

Here, with respect to this specific alternative embodiment of this inducible or repressible transcription factors, it says these factors also carry protein domain as the transactivator, transrepressed, the RNA polymerase 2.

JUDGE LEBOVITZ: Where are you?

MR. PARKER: Sorry. I'm at column 33, page 18, paragraph 110.

So, we submit that Giordano doesn't get you there.

JUDGE ADAMS: It doesn't teach the TetO with the TetR KRAB.

MR. PARKER: Well, it doesn't teach. That's correct, Your Honor. It doesn't teach KRAB. It really just talks about the Tet repressor and Tet operator. It does talk about pol 3, but in the context of the Tet operator, it says use pol 2, only. Now, turning to Deuschle, Deuschle indeed

talks about Tet KRAB system, the combined fusion protein that combines the DNA binding function with the repression function. I was unable to find any suggestion or teaching in here relevant to Si RNA or double-stranded RNA.

JUDGE ADAMS: Well, what are you talking about, a Tet operator? What does that interact with?

MR. PARKER: Well, Your Honor, all I can take as the reference is what they say on their face.

JUDGE ADAMS: Right. That's talking about it – it says operator regulating a promoter element. Here, we have a promoter element regulating Si RNA.

MR. PARKER: Well, I think it's unfair to overly characterize the reference. Again, all I can do is make specific things the reference says; and, we already know from Giordano that.

JUDGE ADAMS: Read the title of the reference in to the record for us. We did that with the Giordano.

MR. PARKER: Yes, tetracycline reversible silencing of eukaryotic promoters.

JUDGE ADAMS: All right. So there's interaction there with regulating promoters?

MR. PARKER: Well, let's see. I think that if you read this reference it makes it very clear that it's talking about pol 2 promoters, entirely. Let me turn to first to the second page of the Deuschle reference and the results section, column 2. It means specifically the T-K promoter. That's the Thymidine Kinase promoter, which is certainly a pol 2 promoter, Thymidine Kinase is an enzyme.

It also talks about the human CMV promoter. That again is a Pol 2 promoter, so there's no mention in here, mention in the results section, of the use of anything other than a pol 2 promoter. There's certainly no mention of anything other than pol 2 promoters any where else in the paper that I can find.

JUDGE ADAMS: Does it talk about other promoters? I mean, just generically, as in of the many different promoters we've tested so far, our KRAB, TetO systems work?

MR. PARKER: It doesn't say that, but I can find it.

JUDGE ADAMS: Let me direct you to it.
MR. PARKER: Okay.
JUDGE ADAMS: 1910, first column, last full sentence. Can you read that into the record, please?
MR. PARKER: Yes. "All of the many different promoters tested so far in this system were found to respond at TetR KRAB mediated silencing equally well. Again, it doesn't tell us what type. They're talking about promoters in the plural. There are two promoters discussed here, and both are pol 2 promoters.
I think that we would be remiss to read into that statement the possibility that they're pol 1 and pol 3 promoters, particularly when read in light of Giordano, which teaches us specifically to use a pol 2 system.
JUDGE LEBOVITZ: Well, let's say we talk about it further and we look at that statement there. And that's many different promoters. They don't show you the data, so the examiner reads that and says, "Okay, I'm reading that. I'm a person of ordinary skill. He is not distinguishing between any class of promoters, so I am going to make that statement and that's my burden of saying that it includes all kinds of promoters, including pol 1, 2 and 3." Okay, so now the burden shifts back to you, and what evidence do you have that that should be restricted to a certain type of promoter.
MR. PARKER: Good point, Your Honor. Giordano. Giordano's point number 1, that's the only other teaching we have. Giordano says pol 2. All right? That's point number two. I've got two more points I'd like to make in the discussion section.
JUDGE ADAMS: Let me just highlight the first comment. The emphasis on Giordano teaching only pol 2 isn't absolutely correct. Giordano teaches a whole variety of different promoter elements, pol 1, 2 or 3, included among them.
MR. PARKER: Absolutely. But it says if you're going to do it as a repressible system, you've got to use pol 2. If you're not using a repressible system, then you can use these other promoters. It says alternatively.
JUDGE ADAMS: Well, maybe I missed that section.
MR. PARKER: All right. I'll be happy to go back to it.

JUDGE ADAMS: It says, "Only use pol 2 when you are talking about a repressible system."

MR. PARKER: Yeah. I'll show you. It says at the top of column 4 in Giordano on page 3. It says, "Alternative to the foregoing, in other words, alternative to the use of RNA polymerase 3 promoter, you can use a Tet promoter."

JUDGE ADAMS: Well, wait. We're at column 4, line 5. Alternatively, the promoter is an inducible promoter such as -- and then he lists the whole list. Okay, a whole list.

MR. PARKER: That's right. That's like our patent application.

JUDGE ADAMS: And we're talking about inducible promoters.

MR. PARKER: Right, and tests the one there at line 12.

JUDGE ADAMS: Is pol 2 or pol 3 an inducible promoter?

MR. PARKER: If it has something added to it.

JUDGE ADAMS: You mean like a cis operator?

MR. PARKER: Yeah.

JUDGE ADAMS: Okay. So we're not really talking about your inducible promoter.

MR. PARKER: Frankly, I've never heard of pol 3 inducible promoters.

JUDGE ADAMS: Yeah, I haven't either.

JUDGE LEBOVITZ: Well, wait.

JUDGE ADAMS: So you're talking about inducible promoters, and you're saying when he talks about inducible promoters, he's talking about pol 2 promoters? That's what you say, right?

MR. PARKER: Yes, absolutely.

JUDGE ADAMS: Well, there's no such thing as an inducible pol 3 promoter?

MR. PARKER: Well, I'm just going by what he says here, Your Honor.

JUDGE ADAMS: That's not what he says.

MR. PARKER: Well, no. We return to paragraph 33. Well, I don't know a Tet promoter that says people refer to this as the Tet promoter, the Tet operator.

JUDGE LEBOVITZ: We're going where?

MR. PARKER: I'm sorry. I was going back to the more specific, detailed description of this general discussion of inducible promoters. The specific discussion is in paragraph 110. And at paragraph 110, again in Giordano, it says that these factors carry protein domains that transactivate the RNA polymerase 2. So the only teaching I can get out of Giordano is if you're going to use inducible, repressible systems, this would teach you on its face to go to pol 2.

Now, let me raise one more issue that I think this board should also take into account, and that is the discussion section. This really kind of goes to the issue of there's a reasonable expectation of success or not.

JUDGE LEBOVITZ: Mr. Parker, sorry.

MR. PARKER: Yes, Your Honor.

JUDGE LEBOVITZ: We were talking about the issue of rebutting the examiner made the points to a statement in a reference which says "all promoters," and now you're going to rebut it and show that it's only pol 2 promoters. And you cited the Giordano reference, which we just discussed. Did you have another point that would rebut that?

MR. PARKER: Yes, Your Honor, and that is in the Deuschle reference.

JUDGE LEBOVITZ: Okay.

MR. PARKER: Okay, so I'm going back to the very reference that Judge Adams referred to for that general statement. And, again, I think you have to read the reference in its entirety, when you, you know, read the section that says, "Many different kinds of promoters." Let's see what kind of promoters they're talking about.

First of all, the only two they mention here, one would think that if a scientist wanted to support a point that said many different promoters and had made some surprising discovery that it worked with something other than pol 2 promoters that that scientist would have put that information in this paper. I'm just saying if I were, in fact, in my day as a scientist, if I was going to make this general statement about promoters, then I'd make something that in fact would have been a little bit surprising that it worked with other promoters as well. I think I might have mentioned the specific results, and yet all they do mention is CMV and bonding Conex.

Let's go on and let's see why.

JUDGE ADAMS: Maybe there's a whole variety of reasons scientists don't do that, in fact. That could be such a surprising discovery that it's another paper. Right?

MR. PARKER: Right. Well, let me go on to point to the additional language I'd like to rely on or to point to for uncertainty, for unpredictability, for lack of showing that there's a reasonable expectation. And this is found on the last page of the text, which is page 1913 of the Deuschle reference, column 2, and figure 9. Let me just read it into the record.

"Further work will have to show whether the silencing exerted by the Tet KRAB protein impinges directly or indirectly on factors of the basal transcription machinery, or if it works by influencing the chromatin structure of the target gene, it is tempting to speculate that KRAB S and P1"-- that's another protein that they say may be involved in this interaction -- "may share some similarity." So the point is, they don't know how it works. They have a model here that says, well, it may work directly on the chromatin, or it may work directly on the RNA polymerase 3. They simply don't know.

But they do talk about Tet KRAB protein. I'm again reading from the last paragraph of the text about halfway down, column 2 again of 1913. Tet KRAB protein offers the unique possibility reversibly downrating the expression of cellular genes on top of their normal cellular regulation. I submit that one of skill in the art reading that would conclude that they're talking about structural genes. Genes that are run by polymerase 2, not polymerase 3 genes.

Generally speaking, polymerase 3 genes are not considered cellular genes. I don't have evidence of that. It's just how I always used it when I was in the laboratory, so. So I think that that excerpt, and one more I'll just point to. Sorry.

JUDGE LEBOVITZ: Let me ask a question.

MR. PARKER: Yes, Your Honor.

JUDGE LEBOVITZ: In reference to your 1913 about you're saying further work will have to show how the silencing mechanism works,

and it talks about the basal transcription machinery. Is the basal transcription machinery different from the pol 1, pol 2, and pol 3?

MR. PARKER: I have no idea what he means by basal transcription mechanism. I don't fully understand figure 9, because in the text he's talking about or by influencing the chromatin structure of the gene. However, when you look at the picture, it looks like the basal transcriptional machinery is the chromatin structure. So I'm not quite sure what is meant by that statement.

JUDGE LEBOVITZ: Yeah, I was wondering whether he was trying to make it out here, whether he was talking about the polymerase, because that's part of the basal transcription machinery.

MR. PARKER: I think that that's what he's talking about, is the polymerase. If I were to speculate, Your Honor, and you said you've got to make a choice, that's what I would pick that to mean, because that's different, I think, from the chromatin structure. The chromatin structure is usually unwinding of things like that.

One more point and then I'll let you folks have it.

JUDGE ADAMS: Okay.

MR. PARKER: And the last point that I'll just point for the record is in column 1 of page 1913, second sentence of the paragraph, Bridging, columns 1 and 2: "The mechanisms by which such alanine-rich or proline rich domains, as well as the KRAB domains, exert their repressing functions, have not yet been identified." So, again, taken together with the other excerpt, they don't know how it works, which I submit limits the ability to predict and advance whether something's going to work or not.

JUDGE ADAMS: Okay, that leads me to my final question for you. And, perhaps, it may be the turning point for us.

We have this tetR KRAB and we know, according to the evidence of record, that this tetR KRAB or KRAB portion recognizes pol 2 or interacts with pol 2. And early on I think it was your understanding or your thoughts that it may also work with pol 3, but that's not in the record or in the evidence of record.

MR. PARKER: No. If I said that, it was inappropriate. I believe that what I followed-up by saying was that I have no idea, and sitting

today I have no idea whether pol 3 promoters are. Maybe I misunderstood your question, but whether pol 3 promoters are inducible or repressible.

JUDGE ADAMS: So how does this, you have this little arrow on our drawing, is linked to the KRAB. And you have this little arrow going over to pol 3. Explain that to me.

MR. PARKER: Well, our discovery is that the tetR with the KRAB in combination with the pol 3 actually has substantial advantages. And I didn't make a big argument about that in the record. Perhaps I should have. I tried to leave the record, but this does provide advantages. It works much better than the tet system alone. In fact, this is currently on the market. This system is being sold by Clone Tech, and it's the preferred system for making Transgenic animals. That's what they use it for, is to make Transgenic animals.

JUDGE ADAMS: Okay. Since we're running short on time, I don't need the history. I just need to make sure we understand. It's known on this record that pol 2 interacts with KRAB. Is that correct?

MR. PARKER: No. It's not.

JUDGE ADAMS: So what is KRAB doing in this? You have this drawing; you have KRAB sitting up there. How does it interact with either pol 2 or pol 3?

MR. PARKER: I drew it that way, Your Honor, because the inventor told me it does.

JUDGE ADAMS: Okay.

MR. PARKER: I don't know anything other than that. That's what Dr. Trono told me it does.

JUDGE LEBOVITZ: But the Deuschle reference tells you that tet KRAB interacts somehow or controls that promoter?

MR. PARKER: No. The Deuschle reference tells you that it interacts, and in my opinion is the reference interacts with pol 2, polymerase 2, RNA polymerase 2.

JUDGE LEBOVITZ: Okay, that's what I meant.

MR. PARKER: Which is a different molecule than RNA polymerase 3 -- lots of different properties.

JUDGE LEBOVITZ: All of these elements were known, okay. We're not disputing that. What we're disputing is whether there would be a

reasonable expectation of success that if tet KRAB would control the pol 3 promoter.

MR. PARKER: That's one of the issues. I would step back and add to that that I don't see the basis for even making up the prima facie case on the would one skilled in the art even go to the pol 3. I think if you read these two references, you don't even go to the pol 3.

JUDGE LEBOVITZ: Got you. You're saying the G reference tells you you wouldn't go to it, but then you're saying look at the Deuschle reference. There's enough ambiguity and unknowns there that one would not reasonably expect that pol 3 could just be mindlessly substituted for pol 2?

MR. PARKER: That's not a bad synopsis of my argument, Your Honor.

JUDGE ADAMS: Any further questions?

JUDGE LEBOVITZ: No.

JUDGE ADAMS: Okay, we can go off the record.

(Whereupon, at 9:45 a.m., the proceedings were concluded.)